APR 0 2 2013

510(k) SUMMARY

K124042

Syneron Beauty's Tanda Mini Skincare System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Syneron Beauty Inc.
11-380 Jamieson Parkway
Cambridge, Ontario, Canada
N3C 4N4

Phone: +1-519-651-1177 X 225
Facsimile: +1-519-651-2277

Contact Person: Bobae Kim

Date Prepared: April 2, 2013

Name of Device and Name/Address of Sponsor

Tanda Mini Skincare System

Syneron Beauty Inc.
11-380 Jamieson Parkway
Cambridge, Ontario, Canada
N3C 4N4

Common or Usual Name

Light Emitting Diode Therapy System

Classification Name

Over-the-counter Powered Light Based Laser for Acne
General and Plastic Surgery Devices Panel
Regulation Number: 21 C.F.R 878.4810
Product Code: OLP

Predicate Device

Syneron Beauty Inc.'s Tanda Skincare System (K080591)

Intended Use / Indications for Use

The Tanda Mini Skincare System is generally indicated to treat dermatological conditions. Specifically, blue light modules are indicated to treat mild to moderate inflammatory acne.

Technological Characteristics

The Tanda Mini Skincare System is a smaller version of its predicate device (K080951) that shares the same principal features and characteristics as the predicate. Both the devices are cordless, handheld units that have a single on/off push button that activates the units. The Tanda Mini Skincare System uses the same technology to deliver blue light at 414 nm to the treatment surface via light emitting diodes (LEDs) as its predicate. Furthermore, there have been no modifications to the safety features of its predicate, which includes a sensor for skin contact and temperature as well as sound indicators. The only changes made in the Tanda Mini Skincare System compared to the previously cleared predicate relates to additional ergonomic features such as a textured treatment surface, and a vibration indicator to signify the treatment is in progress. Furthermore, the total energy dose, dose rate, and treatment regimen remain the same as the previously cleared predicate device.

Performance Data

Risk analysis was performed to assess the modifications to the Tanda Mini Skincare System, and confirmed that no new risks are raised. The following non-clinical performance testing was conducted to re-validate the modified device, against the same test methods and criteria used on the predicate device cleared in K080591 that includes:

- Electrical safety (IEC 60601-1: 2005)
- Electromagnetic compatibility testing (IEC 60601-1-2: 2007)
- Software verification and validation testing and (IEC 62304: 2006)
- Biocompatibility testing (IEC 10993)

In all instances, the Tanda Mini Skincare System functioned as intended.

Substantial Equivalence

The Tanda Mini Skincare System is as safe and effective as the predicate device, the Tanda Skincare System (K080591). The Tanda Mini Skincare System has the same identical intended use and principle of operation as the predicate device. The main safety features that include the skin contact sensor and temperature sensor in the predicate device are also preserved in the Tanda Mini Skincare System. Furthermore, the Tanda Mini Skincare System delivers energy at the same dose and dose rate as the predicate device for the same indication and therefore no new questions of efficacy are raised in the modified device. The minor technical differences in modified ergonomics are directly

correlated to its compact form and do not raise new issues of safety or effectiveness in the modified device compared to the predicate. Verification and validation through software testing, electrical safety and electromagnetic compatibility/interference testing demonstrated that the Tanda Mini Skincare System is as safe and effective as Tanda Skincare System. There were no new hazards identified as a result of these modifications and therefore the Tanda Mini Skincare System is substantially equivalent.

	Syneron Beauty Inc.	**Syneron Beauty Inc (Formerly Pharos Life Corp)**
Device Name	**Tanda Mini Skincare System**	**Tanda Skincare System**
510(k)		**K080591**
Intended Use/Indications for Use	Treatment of mild to moderate inflammatory acne.	Treatment of mild to moderate inflammatory acne.
Energy Type (Technology)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)
Peak Wavelength (nm)	414 nm ± 6	414 nm ± 6
Dose rate (mW/cm^2)	22.4	22.4
Dose (J/cm^2)	12	12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Syneron Beauty
% Hogan Lovells US, LLP
Ms. Janice Hogan
Partner, Regulatory Counsel
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Letter dated: April 2, 2013

Re: K124042
Trade/Device Name: Tanda Mini Skincare System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OLP
Dated: March 04, 2013
Received: March 04, 2013

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K124042

Device Name: Tanda Mini Skincare System

Indications for Use:

The Tanda Mini Skincare System is generally indicated to treat dermatological conditions. Specifically, Blue light modules are indicated to treat mild to moderate inflammatory acne.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.04.02 09:16:00 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K124042